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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,403	04/15/2002	Donald Gullberg	10142.0001	3147

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EXAMINER
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HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,403	<b>Applicant(s)</b> GULLBERG, DONALD	
	<b>Examiner</b> Maher M. Haddad	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26 and 156-162 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 156-162 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 9/7/06, is acknowledged.
2. Claims 26 and 156-162 are pending.
3. Claim 26 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 156-162 are under consideration in the instant application as they read on a recombinant or isolated integrin subunit  $\alpha 11$  having the amino acid sequence encoded by SEQ ID NO: 1.
5. The following new ground of rejections are necessitated by the amendment submitted 9/7/06.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*
7. Claims 156-162 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrase "The mature extracellular domain of integrin subunit  $\alpha 11$  comprising amino acids 23 to 1141 of SEQ ID NO: 2" claimed in claim 156, the phrase "a fragment of the mature extracellular domain of integrin subunit  $\alpha 11$ " claimed in claims 157 and 158, the phrase "mature extracellular domain of integrin subunit  $\alpha 11$ " claimed in claim 161 and the phrase "wherein the mature extracellular domain of integrin subunit  $\alpha 11$  is non-covalently associated with the integrin subunit  $\beta 1$ " claimed in claim 162 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 9/7/06 does not point to the specification for support for the newly added limitations "the mature extracellular domain of integrin subunit  $\alpha 11$  comprising amino acids 23 to 1141 of SEQ ID NO: 2" as claimed in claim 156, "a fragment of the mature extracellular domain of integrin subunit  $\alpha 11$ " as claimed in claims 157 and 158, "mature extracellular domain of integrin subunit  $\alpha 11$ " as claimed in claim 161 and "the mature extracellular domain of integrin subunit  $\alpha 11$  is non-covalently associated with the integrin subunit  $\beta 1$ " as claimed in claim 162. However, the specification does not provide a clear support

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for such limitation. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

8. Claims 156 and 161-162 are rejected under 35 U.S.C. 102(b) as being anticipated by Gullberg *et al* (Dev. Dyn. 204:57-65, 1995) (IDS Ref. No. C2), as is evidenced by Velling *et al* (IDS Ref. No. C5).

Gullberg *et al* teach an isolated integrin subunit  $\alpha$ mt obtained from G6 myoblasts and myotubes. Gullberg *et al* teach that  $\alpha$ mt is induced upon myogenic differentiation (see abstract). Gullberg *et al* teaches that under non-reducing conditions  $\beta$ 1 associated protein migrated as 145 kD, wherein under reducing conditions,  $\beta$ 1 integrin associated protein migrated in SDS-PAGE as a 155 kD protein (see abstract in particular). Gullberg *et al* teach that  $\alpha$ mt $\beta$ 1 heterodimer (see page 60, 2<sup>nd</sup> col., 2<sup>nd</sup> ¶ in particular). While the Gullberg *et al* teachings may be silent as to the "SEQ ID NO: 2" per se; the product is the same as the claimed product. As is evidenced by Velling *et al* that  $\alpha$ 11 is identical with  $\alpha$ mt (see page 25740, 2<sup>nd</sup> col., end of the 1<sup>st</sup> ¶ in particular). Therefore "SEQ ID NO:2" is considered inherent properties.

Gullberg *et al* teach that the changes in the integrin levels were analyzed by immunoprecipitation with anti- $\beta$ 1 integrin IgG (a heterodimer  $\alpha$ mt $\beta$ 1) of surface iodinated and metabolically labeled cultures followed by SDS-PAGE and autoradiography (see Fig.1 in particular).

It is noted that the processing of the signal peptide occurs in the trans-Golgi network. Accordingly, Gullberg's *et al*  $\alpha$ mt on the SDS-PAGE and immunoprecipitation is the mature form of the  $\alpha$ mt.

The reference teachings anticipate the claimed invention.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 27, 2006

*Maher Haddad*

Maher Haddad, Ph.D.  
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